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From: Robert J. Webster, Reg. No. 46,472

To: Commissioner for Patents
unity.comment@uspto.gov
Attn: Robert A. Clarke

Subject: Comments on Proposed Changes to Unity of Invention and Restriction Practice

I respectfully make the following recommendations regarding USPTO Unity of Invention and Restriction Practice:

1. Please consider immediately establishing a Unity/Restriction Specialist Examiner (URSE) designation for those Primary Examiners who demonstrate a thorough knowledge of Unity of Invention principles and practices and Restriction and Election of Species principles and practices, and require that all holdings of Lack of Unity of Invention (LUOI) and all Restriction and Election of Species (RES) determinations/requirements for a period of at least one year be reviewed and approved by URSEs before such determinations and requirements can be communicated, either orally or in writing, to a patent Applicant. Suitable training for URSEs should be conducted, preferably by the skilled USPTO Patent Academy Instructors who routinely teach UOI principles and RES principles. The duties of URSEs should include becoming proficient in unity of invention (UOI) and restriction/election of species (RES) practice and to review every holding of Lack of Unity of Invention (LOUI) and Restriction/Election of Species (RES) requirements and approve every such holding or requirement before it is made. This will not preclude making telephone LOUI holdings or telephone RES requirements, but will require that they be thoroughly thought out and approved before they are made. I have found that

Rationale: a) I was very fortunate to have been an Examining Group SPRE for eight years, during which time I had to thoroughly learn Unity of Invention (UOI) and RES practice on the job based on case-by-case review of scores of LOUI holdings and RES holdings with extremely valuable input from USPTO Patent Academy Instructors on Restriction Practice and from other SPREs and PCT Legal Staff members. Even with that help, it was a long learning experience. Most Examiners do not have the benefit of such experience and it appears that they can definitely benefit from having their holdings of LUOI and RES requirements reviewed by experienced Examiners to make sure that, as a general rule, USPTO LUOI holdings and RES requirements are consistent and correct. If LUOI holdings and RES requirements are inconsistent and incorrect, the consequences to Applicants are frustrating and very time consuming to deal with, and extremely costly.

b) In the Examining Group to which I was assigned, the Group Director required that I review and recommend approval of every holding of LOUI before it was mailed or telephoned to an Applicant. The results of such reviews included extensive revision of many draft LUOI holdings, and withdrawal of many proposed

LUOI holdings. One policy that was implemented by a number of SPREs at that time, with the approval of the PCT legal staff, was that if a protest of a LOUI holding was filed, and the rationale that had been put forth by the Examiner to justify the protested LOUI was improper, regardless of whether a LOUI existed in that case, then the protest was granted and all pending claims had to be examined on their merits. This policy gave the Examiners an incentive to make a proper LOUI holding in the first place and appeared to be fair to Applicants. I recommend this policy be also be immediately implemented throughout the Examining Corps.

c) Since retiring from the USPTO, I have responded to dozens of RES holdings and a handful of LOUI holdings. In my opinion, based on my 8 years of reviewing LOUI holdings and RES petitions as a SPRE, and as a patent practitioner who has responded to dozens of RES requirements and a few LOUI requirements, many of the LOUI and RES holdings are simply improper in that they do not follow the established guidelines in Chapter 800 of the MPEP and in Annex B, pages AI-58-AI-71of the MPEP.

d) The types of RES requirements pertaining to presumably related inventions do not appear to be as easy to understand or explain, and Examiners appear to often misstate what types of related inventions are being claimed and/or incorrectly apply the tests for distinctness of related inventions set forth in the MPEP. The most improper categories of restriction requirements appear to be (1) different statutory categories of invention, (2) combination-subcombination inventions (the only RES category that requires a showing of two-way distinctness); (3) and subcombinations usable together (which often turn out to really be combination-subcombination inventions or different species). Quite often when restriction is being made between different statutory categories of invention, the Examiner does not treat the invention "as claimed," as required by the Manual of Patent Examining Procedure (MPEP).

e) The many RES requirements that I have reviewed both as a SPRE, and as a patent practitioner, seem to be proper mainly when the Examiner makes an election of species requirement. In my experience, election of species requirements under 35 USC §121 appear to be readily understood by most Examiners and usually are properly made under existing MPEP guidelines. There are rare exceptions to this, such as, for example, when Examiners improperly base election of species requirements in terms of claims instead of disclosed embodiments, contrary to guidance in MPEP §1800.

2. Please consider making determinations of undue administrative burden on Examiners more objective. One area of concern that Applicants have with existing election of species requirements is that there is no incentive for an Examiner to make a meaningful evaluation of what constitutes undue administrative burden under MPEP §803. For example, I personally have seen instances when I was reviewing a petition under Rules 181 and 144 where I could not believe that an election of species was made because of the ease with which the two or three disclosed species could be searched and examined. In other words, I never would have required restriction in those cases because of the relatively ease of performing a reasonably comprehensive search of those few species. Sometimes, for example, the difference between the disclosed species is

addition or deletion of a conventional feature. In those instances, an election of species would not be proper at least because there would be no undue burden on the Examiner to search and examine all species. On the other hand, I often agreed with Examiners that the species were so different and the search so different among species, that search and examination of more than one species would have been unduly burdensome. To address this issue, I recommend that every review of a proposed LOUI holding and of a RES requirement (for example, by a URSE) involve a meaningful evaluation of whether searching and examining more than one species would involve an undue search and examination burden on the Examiner. Such evaluations should be supported by objective factual evidence to be fully in compliance with the Administrative Procedures Act.

3. Please consider determining what constitutes a reasonable number of species prior to examination on the merits.

a.1) In general, existing election of species practice provides that once an allowable generic claim is found, Applicant is permitted claims to a reasonable number of species as long as they depend from the allowed generic claim (as an aside, I assume that writing an identical number of independent claims with the allowable generic claim features would also be permitted). If this practice is permissible, then why not require Examiners to search and examine a reasonable number of species from the outset? In other words, if the Office can determine what a reasonable number of species is after examination of a single species and determination of an allowable generic claim, then the Office should be able to determine before examination, what a reasonable number of species is. A reasonable number of species may be just one but may be more, and the Examiner should objectively evaluate this issue.

a.2) Determining what a reasonable number of species is beforehand is similar to what is involved in a UOI determination, where claims having allowable commonly recited technical features have to be identified before unity of invention is found to exist. In the UOI situation, the Examiner has to review the claims ahead of time, determine the existence or nonexistence of commonly recited technical features, and determine whether or not those commonly recited features are special, regardless of whether an election of species situation is presented. Both of these determinations differ significantly from what has to be determined in the USPTO's current RES practice, where the Examiner never has to examine more than one species regardless of whether there is an allowable generic claim. From an Applicant's perspective, it is more beneficial to have a reasonable number of species examined at the outset and the best chance to have that happen is to have the OUI standards apply. This may require an overall increase in patent application fees, but it should result in fewer total patent applications being filed and fewer patents being granted with respect to which maintenance fees will have to be paid, thereby reducing the number of total applications prosecuted by an Examiner and the total number of patents that will be granted for which Applicants will have to pay Issue fees and Maintenance fees.

a.3) Because species are presumed to be independent inventions, i.e., inventions that have no disclosed or apparent relationship, the USPTO should state that fact before restriction or election of species is made so that both Examiners and Applicants will appreciate the difference between independent inventions and distinct-but-related inventions before a restriction or election of species is made and so that Applicants who receive a restriction or election of species requirement concerning independent inventions will also appreciate that difference.

b.1) In the area of Biotechnology, the issue of how to effectively handle genus-species inventions is very important. It appears to me that most biochemistry art Examiners are stretched to the limits to do a reasonably comprehensive search of such patent applications, especially those that disclose and claim nucleotide sequences. Unfortunately, according to attorneys who I have spoken to about this issue, this has led to almost a *per se* rule of examining only one species within a generic claim, which significantly increases costs to Applicants who have to file many, many applications to cover their different species inventions.

b.2) According to those biotechnology attorneys, justification for this policy is usually based on a statement in the RES requirement that each of the sequences possesses differences in structure and function and are therefore distinct from each other.

b.3) Regardless of the merits of such arguments, to aid the biotechnology industry in protecting its intellectual property, the Commissioner has previously partially waived the requirements of 37 C.F.R. §1.141 *et seq*. to permit a "reasonable number" of nucleotide sequences to be claimed in a single application. *See Examination of Patent Applications Containing Nucleotide Sequences*, 1192 OG 68 (November 19, 1996).

b.4) Moreover, MPEP §803.04 (Eighth Edition, May 2004 revision) explains that normally 10 sequences constitute a "reasonable number" of sequences for examination purposes. Thus, 10 independent and distinct nucleotide sequences should be examined in a single application without restriction. Exceptional cases which are outside of this practice include amino acid sequences reciting 3-dimensional folding.

b.5) However, apparently the USPTO has now decided that a "reasonable number" of sequence is one. Justification for such decision is the administrative burden upon the Examiner. However, this policy conflicts with the earlier precedent set out by the Office, i.e., the same precedent upon which the public relied.

b.6) Note that these arguments are equally applicable to U.S. national phase application entering the USPTO under §371. Attention is drawn to the Commissioner's *sua sponte* decision to partially waive 37 C.F.R. § 1.475 and 1.499 *et seq.* to permit Applicants to claim up to ten (10) nucleotide sequences that do not have the same or corresponding special technical feature. See, in this regard, MPEP § 1850 under the heading "Unity of Invention – Nucleotide Sequences" (see MPEP pages 1800-103&104, May 2004 Revision). This is also consistent with the Commissioner's

treatment of regular United States applications. *See Examination of Patent Applications Containing Nucleotide Sequences*, 1192 OG 68 (November 19, 1996).

4. Please consider requiring the USPTO to make a UOI evaluation in all Applications.

a) If the USPTO continues not to look at patentabililty when making RES requirements, one result will most probably be more patent applications being filed directed to non-elected inventions, resulting in more and more applications having to be examined by the existing number of patent Examiners. It would appear to be in the USPTO's best interests, as well as Applicants best interests, to examine more inventions per patent application. One way to achieve this would be to require a UOI standard to be used instead of existing U.S. RES practice.

b) In this regard, i.e., if a UOI standard requiring determination of commonly recited special technical features is adopted, I recommend not adopting the fourth option proposal by the USPTO to permit Examiners to assume that commonly recited technical features are not special, and requiring Applicants to prove that those commonly recited technical features are "special," i.e., have novelty and are not obvious, because such a policy would appear to contravene established case law that places the burden of establishing a *prima facie* case or unpatentability on the USPTO and require Applicants to speculate about patentability of their invention without having the benefit of a reasonably comprehensive search of prior art. This fourth option proposal by the USPTO would place Applicants in an impossible situation of having to establish a *prima facie* case of novelty and non-obviousness of their invention before a patent Examiner reaches the merits of their invention. Moreover, it would not be unexpected that the USPTO would try to use whatever statements made by Applicants in a pre-examination-on-the-merits stage of a patent application against Applicants in later prosecution on the merits, thereby creating another source for estoppel against Applicants. Moreover, if this fourth option proposal were adopted, patent Examiners would have an incentive to make holdings of LOUI and RES in as many applications as possible to shift their established burden of making out a *prima facie* case of unpatentability before the merits of the application was reached. Accordingly, I recommend that the USPTO's fourth option proposal to permit Examiners to assume that commonly recited technical features of the claims are not special not be accepted.

5. Please consider requiring a Two-Way Distinctness Test in all UOI determinations and RES requirements.

a.) The USPTO's current restriction practice generally requires one-way distinctness between related inventions to require restriction. Similarly, in patent interference practice, to show that a claim of a party's involved application or patent corresponds to a count, the moving party has to only demonstrate one-way distinctness between the claim and the count. However, to have a patent interference declared, an Applicant must demonstrate two-way distinctness between the Applicant's claims and the claims of the other party's application or patent in order to have a patent interference

declared. This is a double standard that should be harmonized. If an Applicant has to demonstrate two-way distinctness to have a patent interference proceeding declared to thereby determine patentability issues as well as priority of invention issues with respect to another patent or application, then the USPTO should have to show two-way distinctness between an Applicant's disclosed and claimed related inventions (as they currently do for combination-subcomination inventions) in order to restrict between related inventions. In other words, I recommend that two-way distinctness be shown in all restriction requirements concerning related inventions.

6. Please consider adopting UOI standards for all UOI and RES issues.

a) I recommend adhering to UOI practice for all U.S. patent applications, whether they are filed under 37 CFR §371, or 35 USC §111a, especially for Small Entity status Applicants. I have a difficult time explaining UOI and RES practice to small entity clients, let alone trying to justify the expenses of traversing LOUI holdings in a 35 USC 371 application and than trying to explain that once we file continuing 35 USC 111a applications, the ground rules change and restriction becomes even easier for USPTO Examiners, who are significantly interested in increasing their productivity without regard to the extra expense they subject small entity Applicants to when those Applicants have to file many more continuing applications that they would have had to file had the UOI standards remained in effect for the 35 USC §111a applications.

7. Please consider maintaining current avenues of review of LUOI holdings and RES requirements.

a) I recommend retaining all of the existing avenues of review of LOUI and RES determinations by Examiners, based on the current apparently large number of improper restriction requirements being made, i.e., retain Rule 181 petitions to the Examining Group Directors, as well as Rule 182 and 183 petitions to the Commissioner, before having to go to a Federal District Court under the Administrative Procedures Act. I also recommend keeping the status quo in this regard because of the expense involved in the number of additional patent applications that need to be filed based on restricted-out inventions.

8. Please consider requiring consistent treatment of applications filed under 35 USC §371 and 35 USC §111a that are based on the same PCT application.

a) I recommend giving Applicants the option of retaining UOI standards when filing "by-pass" or continuing 35 USC §111a applications based on PCT applications, instead of having to go to considerable effort and expense protesting Unity of Invention determinations in an International Application or a National Application filed under 35 USC §371 and then be subjected to a very different set of rules regarding RES requirements. I recommend that this option be exercised prior to a first Office Action in each of the 35 USC §111a applications.

SUMMARY

I recommend (1) establishing a category of LUOI and RES requirement experts in all Examining Groups and requiring that all LUOI and RES determinations be reviewed by such expert Examiners in each examining group before a LUOI or RES requirement can be made in an application, either orally or in writing; (2) requiring an Examiner to examine all pending claims if the Examiner makes a LOUI determination or RES requirement that does not set forth a *prima facie* case of lack of unity of invention or of a proper restriction or election of species requirement in accordance with the policy guidance found in the MPEP; (3) retaining the existing avenues and levels of review of LUOI and RES holdings including petitions under 37 CFR §§1.181, 1.182 and 1.183 within the USPTO; (4) using a LUOI standard instead of a RES standard in all U.S. patent Applications filed under 35 USC §111a or, as an option, in all applications filed under 35 USC §111a that are bypass applications or continuation applications of national stage applications filed under 35 USC §371, at Applicant's option; (5) require a meaningful evaluation by an Examiner and a URSE of whether examining more than one disclosed and claimed species would involve an undue search and examination burden on the Examiner, supported by a statement based on objective factual evidence; and (6) in applications where an election of species requirements for independent inventions is proper, whether under LUOI or RES standards, establish a presumption, depending on the art involved, of how many species should examined as a reasonable number before there is a substantial administrative burden on the Examiner. This presumption can be rebutted on a case-by-case basis, but will require a detailed rationale set forth by the Examiner that is supported by objective factual evidence to rebut. This last proposal will require input from the public and from Examiners. The guidance set forth in MPEP §§803.04 and 1850 should be taken into consideration in this determination.

RECOMMENDATIONS CONCERNING THE USPTO'S FOUR OPTIONS

1. I do not recommend retaining the current 35 USC §121 independent or distinct standard for restriction. As noted above, I recommend using the UOI standards and determining a reasonable number of species prior to examination on the merits and examination of all those species at the current patent examination cost.

2. I *partially* support option 2, the modified PCT Unity of Invention (UOI) standard. The showing by an Examiner that the main claim is not fully supported should to be explained in more detail than it is in the study. For example, if lack of enablement is the basis for lack of unity, will a complete discussion of all the "Wands" factors, discussed in MPEP §706.03(a) and §2164.01(a) have to be presented? Furthermore, in this regard, will Applicant be given a chance to amend the main claim to overcome a determination of lack of compliance with 35 USC §112, first paragraph?

I respectfully submit that (1) enablement and written description issues are best handled after unity of invention issues have been resolved (otherwise, the §112, first paragraph issues will be addressed on the merits in the preliminary UOI stage and in the later examination-on-the-merits stage, and this type of determination at the UOI stage will just result in piecemeal prosecution); and (2) the UOI standard gives Applicants a better chance of having a reasonable number of related inventions examined in a single application.

3. The third option, i.e., the three-tiered option, is very difficult to put into practice. As noted above, the USPTO guidelines for inventions involving nucleotide sequences indicate that up to 10 species will be considered a reasonable number of species yet, in actual practice, the USPTO appears to limits its search and examination to one of the claimed species. There simply is no incentive for to USPTO to search and examine more than one of those sequences. This option appears unworkable at present.

4. The fourth option, i.e., an independent and distinct test, appears to only apply to species not usable together. The suggestion that inventions are distinct if they are patentable over each other fails to address whether a one-way or a two-way patentable distinctness test is employed – both tests being employed in patent interference proceedings, as noted above. Before any such standard is adopted, the USPTO should be required to take consistent positions on whether inventions are patentably distinct, i.e., on a one way or a two-way basis. The inclusion in this option of requiring satisfaction of the enablement and written description requirements of 35 USC §112, first paragraph does not seem like a good idea for the reasons discussed above, including piecemeal prosecution problems. The inference that common technical features define over the prior art is contrary to established case law which places the burden of establishing a *prima facie* case of unpatentability of a claimed invention, and will improperly give rise to estoppel against Applicants based on arguments presented by Applicants to establish a *prima facie* case of patentability.